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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/020,450      | 12/14/2001  | Guy Michael Miller   | 346392000900        | 1698             |

25226 7590 04/12/2004  
MORRISON & FOERSTER LLP  
755 PAGE MILL RD  
PALO ALTO, CA 94304-1018

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT PAPER NUMBER

1614

DATE MAILED: 04/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

*Central*

# Office Action Summary

Application No.

10/020,450

Applicant(s)

MILLER ET AL

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,9-23,33-38,42-47 and 51-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,9-23,33-38,42-47 and 51-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Art Unit: 1614

The indicated allowability of claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 in Paper No. 25 mailed November 14, 2003, is withdrawn in view of the newly discovered references to Wechter, W.J. (US 2004/0029954, US 2004/0058986, US 2004/0058987). Rejections based on the newly cited references follow. Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 remain under consideration.

An Information Disclosure Statement filed November 11, 2003, Paper No. 25, is acknowledged. All of the cited references have previously been reviewed. Copies of these PTO-1449 Forms that are initialed by the Examiner are enclosed.

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitation "a non-alpha-tocopherol enriched tocopherol composition" renders the claims indefinite. While the presence of non-alpha tocopherols is required in the claimed composition, the language of claim 1 does not preclude other types of tocopherols. Accordingly, the claims lack clarity in that the open language employed permits any other active ingredient including alpha-tocopherols. Clarification is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 1614

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 are rejected under 35

U.S.C. 102(e) as being anticipated by Wechter, W.J., U.S. 2004/0058987.

Wechter teaches methods for treating and/or ameliorating the symptoms of a cerebral ischemic condition in a mammalian subject comprising administering a non-alpha tocopherol enriched tocopherol composition to reduce neuronal damage related to said cerebral ischemic condition. See page 9 where dosages and various formulations are disclosed.

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 are rejected under 35

U.S.C. 102(e) as being anticipated by Wechter, W.J., US 2004/0058986.

Wechter teaches methods of treating and/or ameliorating the symptoms of a noncardiovascular tissue ischemic condition comprising administering a gamma-tocopherol enriched tocopherol composition. While the presence of gamma tocopherols is required in Wechter's teaching, the language of claim 1 does not preclude other types of tocopherols. Accordingly, other tocopherols, alpha-, beta- and delta-, are reasonably encompassed in Wechter's compositions. Non-cardiovascular tissue ischemic conditions include spinal cord ischemia, peripheral nerve damage and neuropathies. Thus a reduction of neuronal damage would occur following treatment of ischemia in these noncardiovascular tissues. See page 9 where dosages and various formulations are disclosed.

Art Unit: 1614

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-64 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter, W.J. US 2004/0029954.

Wechter broadly claims methods of treating or preventing any ischemic condition comprising administering a composition comprising tocopherols, at least 50% of which being  $\gamma$ -tocopherol. Claimed ischemic conditions include those associated with the brain, the nervous system and the eye. The claims differ in that the present claims recite "a non-alpha tocopherol enriched tocopherol composition" and "for treating and/or ameliorating a symptom of neuronal damage associated with a cerebral ischemic condition". However, one skilled in the art would have considered the recited compositions, "a non-alpha tocopherol enriched tocopherol composition" to comprise other tocopherols. The open language of the present claims allows for the addition of any number of other active ingredients in the composition. Further, it would have been reasonable to expect an improvement in an ischemic condition of the brain, i.e., an improvement in blood supply to the brain, would result in a reduction of neuronal damage associated with ischemia. The determination of optimal concentrations and optimal dosage forms are parameters well within the purview of those skilled in the art through no more than routine experimentation.

Art Unit: 1614

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 6, 9-23, 33-38, 42-47 and 51-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 11-13, 22, 31-33, 42, 53-57 and 98 of copending Application No. 10/017717. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*DPat needed*

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis G.

Spivack at telephone number 571-272-0585.

*Phyllis Spivack*

Phyllis G. Spivack  
Primary Examiner  
Art Unit 1614

April 7, 2004

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**